incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

139. The method of claim 138, wherein the step of administering comprises infecting cells of the warm-blooded animal ex vivo with the viral vector and subsequently delivering the infected cells to the warm-blooded animal.

B2

140. (new) The method of claim 138, wherein the composition comprises a lipid.

141. (new) The method of claim 138, wherein the composition comprises a physiologically acceptable carrier or diluent.

142. (new) The method of claim 138, wherein the viral vector is an adenoviral vector.

143. (new) The method of claim 138, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:6.

144. (new) The method of claim 138, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:7.

REMARKS

New claims 113-144 are submitted for examination. Appendix A provides the Version with Markings to Show Changes Made. Appendix B provides the pending claims.

Response to restriction requirement

In response to the restriction requirement, Applicants elect Group I, claim 93 in part, and claims 97-102 in part, which recite a fusion of SEQ ID NO:3 to SEQ ID NO:4. The fusion of SEQ ID NO:3 (human ECD) to SEQ ID NO:4 (human PD) recited in claims 93 and 97-102 corresponds to SEQ ID NO:6 (human ECD-PD), as claimed in the newly presented claims 113-144. Therefore, new claims 113-144 correspond to elected Group I.

Claim support

Claims 113, 127, and 138 have been added. These claims recite methods of eliciting an immune response by administering a HER-2/neu fusion protein or a nucleic acid encoding a HER-2/Neu fusion protein, where the protein is encoded by a nucleic acid sequence that hybridizes under specified hybridization conditions to a nucleic acid sequence encoding an amino acid sequence of SEQ ID NO:6. These claims add no new matter. Support for these claims can be found, e.g., in the specification on page 8, lines 7-13; page 11, line 31 to page 12, line 5; and on Figure 12.

Claims 115, 116, 136, 137, 143, and 144 have been added. These claims add no new matter. Support for these claims can be found, e.g., in Figures 12 and 13.

Claim 117 has been added to recite a lipidated fusion protein. This claim adds no new matter. Support for this claim can be found, e.g., in the specification on page 18, lines 9-15, and on page 32, lines 18-19.

Claims 118, 131, and 141 have been added to recite a physiologically acceptable carrier or diluent. These claims add no new matter. Support for these claims can be found, e.g., in the specification on page 48, line 11.

Claims 120 and 124 have been added to recite a composition comprising tocopherol. These claims add no new matter. Support for these claims can be found, e.g., in the specification on page 51, line 32 to page 52, line 3.

Claim 125 has been added to recite a composition comprising a CpG-containing oligonucleotide. This claim adds no new matter. Support for this claim can be found, e.g., in the specification on page 46, 23-25.

Claims 130 and 140 have been added to recite a composition comprising a lipid. These claims add no new matter. Support for these claims can be found, e.g., in the specification on page 37, line 25; page 45, line 17-19; page 48, line 15; and page 50, line 17-18.

Claims 133, 135, and 142 have been added to recite an adenoviral vector. These claims add no new matter. Support for these claims can be found, e.g., in the specification on page 49, lines 9-10.

Claims 114, 119, 121, 122, 123, 126, 128, 129, 132, 134, and 139 have been added. These claims add no new matter. Support for these claims can be found, e.g., in the claims as originally filed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Annette S. Parent
Reg. No. 42,058

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: (415) 576-0300
ASP:dk
SF 1392662 v1

APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please amend the specification on page 52, lines 4-10, as follows:

Other preferred adjuvants include Montanide ISA 720 (Seppic, France), SAF (Chiron, California, United States), ISCOMS (CSL), MF-59 (Chiron), [the SBAS series of adjuvants (*e.g.*, SBAS-2 or SBAS-4, available from SmithKline Beecham, Rixensart, Belgium),] Detox (Corixa Corporation, Hamilton, MT), RC-529 (Corixa, USA) and Aminoalkyl glucosaminide 4-phosphates (AGPs).

In a preferred embodiment, the adjuvant is [SBAS-2 (*See, e.g.*,] described in EP 735898B1[)].

IN THE CLAIMS:

Please cancel claims 93-112 without prejudice to subsequent revival.

Please add new claims 113-144 as follows.

113. (new) A method for eliciting or enhancing an immune response to HER-2/neu protein, the method comprising the step of administering to a warm-blooded animal a composition comprising an isolated protein comprising a Her2/Neu ECD-PD fusion protein in an amount effective to elicit or enhance the immune response, the Her-2/neu ECD-PD fusion protein comprising a Her-2/neu extracellular domain fused to a Her-2/neu phosphorylation domain, wherein the fusion protein is encoded by a nucleic acid that hybridizes under stringent conditions to the complement of a nucleic acid sequence encoding an amino acid sequence of SEQ ID NO:6, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and

wherein the protein is capable of producing an immune response in a warm-blooded animal.

114. (new) The method of claim 113, wherein the composition is administered in the form of a vaccine.

115. (new) The method of claim 113, wherein the fusion protein comprises an amino acid sequence of SEQ ID NO:6.

116. (new) The method of claim 113, wherein the fusion protein comprises an amino acid sequence of SEQ ID NO:7.

117. (new) The method of claim 113, wherein the fusion protein is lipidated.

118. (new) The method of claim 113, wherein the composition comprises a physiologically acceptable carrier or diluent.

119. (new) The method of claim 118, wherein the composition comprises an oil-in-water emulsion.

120. (new) The method of claim 119, wherein the composition comprises tocopherol.

121. (new) The method of claim 113, wherein the composition comprises an immunostimulatory substance.

122. (new) The method of claim 121, wherein the composition comprises an immunostimulatory substance comprising 3D-MPL, QS21, or a combination of 3D-MPL and QS21.

123. (new) The method of claim 121, wherein the composition comprises an immunostimulatory substance comprising 3dMPL and QS21 in an oil-in-water emulsion.

124. (new) The method of claim 123, wherein the composition comprises tocopherol.

125. (new) The method of claim 113, wherein the composition comprises a CpG-containing oligonucleotide.

126. (new) The method of claim 113, wherein the step of administering comprises transfecting cells of the warm-blooded animal ex vivo with the composition comprising the fusion protein and subsequently delivering the transfected cells to the warm-blooded animal.

127. (new) A method for eliciting or enhancing an immune response to HER-2/neu protein, the method comprising the step of administering to a warm-blooded animal a composition comprising a nucleic acid molecule encoding a HER-2/neu fusion protein in an amount effective to elicit or enhance the immune response, the HER-2/neu fusion protein comprising a HER-2/neu extracellular domain fused to a HER-2/neu phosphorylation domain, wherein the nucleic acid hybridizes under stringent conditions to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:6, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and

0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

128. (new) The method of claim 127, wherein the nucleic acid molecule is in the form of a vaccine.

129. (new) The method of claim 127, wherein the step of administering comprises transfecting cells of the warm-blooded animal *ex vivo* with the composition comprising the nucleic acid molecule and subsequently delivering the transfected cells to the warm-blooded animal.

130. (new) The method of claim 127, wherein the composition comprises a lipid.

131. (new) The method of claim 127, wherein the composition comprises a physiologically acceptable carrier or diluent.

132. (new) The method of claim 127, wherein the nucleic acid molecule is a viral vector encoding a HER-2/neu fusion protein.

133. (new) The method of claim 127, wherein the viral vector is an adenoviral vector.

134. (new) The method of claim 129, wherein the nucleic acid molecule is a viral vector encoding a HER-2/neu fusion protein.

135. (new) The method of claim 134, wherein the viral vector is an adenoviral vector.

136. (new) The method of claim 127, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:6.

137. (new) The method of claim 127, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:7.

138. (new) A method for eliciting or enhancing an immune response to HER-2/neu protein, the method comprising the step of administering to a warm-blooded animal a composition comprising a viral vector comprising a nucleic acid molecule encoding a HER-2/neu fusion protein in an amount effective to elicit or enhance the immune response, the HER-2/neu fusion protein comprising a HER-2/neu extracellular domain fused to a HER-2/neu phosphorylation domain, wherein the nucleic acid hybridizes under stringent conditions to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:6, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

139. The method of claim 138, wherein the step of administering comprises infecting cells of the warm-blooded animal ex vivo with the viral vector and subsequently delivering the infected cells to the warm-blooded animal.

140. (new) The method of claim 138, wherein the composition comprises a lipid.

141. (new) The method of claim 138, wherein the composition comprises a physiologically acceptable carrier or diluent.

142. (new) The method of claim 138, wherein the viral vector is an adenoviral vector.

143. (new) The method of claim 138, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:6.

144. (new) The method of claim 138, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:7.

APPENDIX B
PENDING CLAIMS

113. (new) A method for eliciting or enhancing an immune response to HER-2/neu protein, the method comprising the step of administering to a warm-blooded animal a composition comprising an isolated protein comprising a Her2/Neu ECD-PD fusion protein in an amount effective to elicit or enhance the immune response, the Her-2/neu ECD-PD fusion protein comprising a Her-2/neu extracellular domain fused to a Her-2/neu phosphorylation domain, wherein the fusion protein is encoded by a nucleic acid that hybridizes under stringent conditions to the complement of a nucleic acid sequence encoding an amino acid sequence of SEQ ID NO:6, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

114. (new) The method of claim 113, wherein the composition is administered in the form of a vaccine.

115. (new) The method of claim 113, wherein the fusion protein comprises an amino acid sequence of SEQ ID NO:6.

116. (new) The method of claim 113, wherein the fusion protein comprises an amino acid sequence of SEQ ID NO:7.

117. (new) The method of claim 113, wherein the fusion protein is lipidated.

118. (new) The method of claim 113, wherein the composition comprises a physiologically acceptable carrier or diluent.

119. (new) The method of claim 118, wherein the composition comprises an oil-in-water emulsion.

120. (new) The method of claim 119, wherein the composition comprises tocopherol.

121. (new) The method of claim 113, wherein the composition comprises an immunostimulatory substance.

122. (new) The method of claim 121, wherein the composition comprises an immunostimulatory substance comprising 3D-MPL, QS21, or a combination of 3D-MPL and QS21.

123. (new) The method of claim 121, wherein the composition comprises an immunostimulatory substance comprising 3dMPL and QS21 in an oil-in-water emulsion.

124. (new) The method of claim 123, wherein the composition comprises tocopherol.

125. (new) The method of claim 113, wherein the composition comprises a CpG-containing oligonucleotide.

126. (new) The method of claim 113, wherein the step of administering comprises transfecting cells of the warm-blooded animal ex vivo with the composition

comprising the fusion protein and subsequently delivering the transfected cells to the warm-blooded animal.

127. (new) A method for eliciting or enhancing an immune response to HER-2/neu protein, the method comprising the step of administering to a warm-blooded animal a composition comprising a nucleic acid molecule encoding a HER-2/neu fusion protein in an amount effective to elicit or enhance the immune response, the HER-2/neu fusion protein comprising a HER-2/neu extracellular domain fused to a HER-2/neu phosphorylation domain, wherein the nucleic acid hybridizes under stringent conditions to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:6, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

128. (new) The method of claim 127, wherein the nucleic acid molecule is in the form of a vaccine.

129. (new) The method of claim 127, wherein the step of administering comprises transfecting cells of the warm-blooded animal *ex vivo* with the composition comprising the nucleic acid molecule and subsequently delivering the transfected cells to the warm-blooded animal.

130. (new) The method of claim 127, wherein the composition comprises a lipid.

131. (new) The method of claim 127, wherein the composition comprises a physiologically acceptable carrier or diluent.

132. (new) The method of claim 127, wherein the nucleic acid molecule is a viral vector encoding a HER-2/neu fusion protein.

133. (new) The method of claim 127, wherein the viral vector is an adenoviral vector.

134. (new) The method of claim 129, wherein the nucleic acid molecule is a viral vector encoding a HER-2/neu fusion protein.

135. (new) The method of claim 134, wherein the viral vector is an adenoviral vector.

136. (new) The method of claim 127, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:6.

137. (new) The method of claim 127, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:7.

138. (new) A method for eliciting or enhancing an immune response to HER-2/neu protein, the method comprising the step of administering to a warm-blooded animal a composition comprising a viral vector comprising a nucleic acid molecule encoding a HER-2/neu fusion protein in an amount effective to elicit or enhance the immune response, the HER-2/neu fusion protein comprising a HER-2/neu extracellular domain fused to a HER-2/neu phosphorylation domain, wherein the nucleic acid hybridizes under stringent conditions to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:6, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

139. The method of claim 138, wherein the step of administering comprises infecting cells of the warm-blooded animal ex vivo with the viral vector and subsequently delivering the infected cells to the warm-blooded animal.

140. (new) The method of claim 138, wherein the composition comprises a lipid.

141. (new) The method of claim 138, wherein the composition comprises a physiologically acceptable carrier or diluent.

142. (new) The method of claim 138, wherein the viral vector is an adenoviral vector.

143. (new) The method of claim 138, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:6.

144. (new) The method of claim 138, wherein the nucleic acid molecule encodes a protein comprising an amino acid sequence of SEQ ID NO:7.